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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,869	12/03/2001	Orest W. Blaschuk	100086.407C7	1299

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/30/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,869

Applicant(s)

BLASCHUK ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 63-68 and 105-117 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14, 63-68, 105-117 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claims 15-62 and 69-104 have been cancelled. Claims 1-14, 63-68, and 105-117 are under consideration by the examiner.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 13-14, 63-66, and 105-117, drawn to modulating agents, classified in at least for example, Class 530, subclass 324.
- II. Claims 9-11 and 67, drawn to polynucleotides encoding modulating agents, classified in at least for example Class 536, subclass 23.5.
- III. Claims 12 and 68, drawn to antibodies, classified in at least for example Class 530, subclass 387.1.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct sequences and a further restriction is applied to each Group. Applicant must further elect a single amino acid sequence (**not** the generic formula of SEQ ID NO: 3 in which seven of nine positions is a wild-card). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

The examiner notes that all of the SEQ ID NOS. present in the claims appear to fall within the structure of SEQ ID NO: 3 or a subsequence thereof. The examiner further notes that subsets of claims are directed to at least fifteen different families of cadherins (e.g. OB-cadherin, cadherins 5-8, etc.). Based upon the diversity of sequences encompassed by the generic formula of SEQ ID NO: 3 in which seven of nine positions is a wild-card and the sequence diversity among the recited cadherin families, arguments that there is no burden of search or that the claimed sequences are all related and should be examined together will not be persuasive. Because SEQ ID NO: 3 is largely undefined this cannot be considered a common core structure, particularly as many of the embodiments encompassed are not found in the different families of cadherins. That is, it is not a proper genus/species situation. It is further noted that many of the claims are directed to a recited sequence embedded in a larger undefined sequence. The examiner would consider examining more than the number of elected sequences set forth above (based upon which group is elected) if a more limited genus with a completely defined core

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structure could be identified that did not require an undue burden of search. It appears from a cursory examination of the specification and specific SEQ ID NOS. as well as the formula of claim 8 that the minimum size of modulating agent contemplated is five amino acids. Applicant is cautioned against introducing new matter with respect to unsupported subgenuses. If applicant traverses or argues for rejoinder or examination of larger numbers of sequences (except as outlined above), applicant should provide or point to evidence showing the different modulating agents as obvious variants of each other or clearly admit on the record that this is the case. Absence of such a statement with this type of traversal or request for rejoinder will be viewed as being non-responsive. Applicant is requested to identify all claims and/or SEQ ID NOS. that read upon their election.

Examination will be restricted to only the elected sequences.

The inventions are distinct, each from the other for the following reasons.

Each of the products of groups I-III can be shown to be distinct, each from the other, because each product is structurally and functionally different. They do not require each other for their ultimate use. Furthermore, each of the products has multiple, distinct uses. The modulating agents can be used in therapy and to make antibodies. The polynucleotides can be used to make proteins and as hybridization probes. The antibodies can be used in therapy and to purify proteins. Each product would require a non-coextensive literature search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification as well as the requirement for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
April 28, 2003